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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,773	11/14/2001	Kiamars Hajizadeh	3873 P 011	1833

7590 02/08/2006

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,773	HAJIZADEH, KIAMARS	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 November 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-8,13-18,20-26,29-34 is/are rejected.
- 7) Claim(s) 3,9-12,19,27 and 28 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicant's Response to Office Action, received 14 November 2005, is acknowledged.

Claims 1, 9, 14, 25, 28, 30, and 33 have been amended.

Applicant lists claims 3, 19, and 27 are listed as "withdrawn". It is unclear what is meant by this disposition. If the claims are to be deleted, they should be so marked. However, until such time as the claims 3, 19, and 27 are deleted, they remain pending and under consideration.

2. Claims 1-34 are pending and under consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Newly amended claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As now amended, claim 1 is a method for detecting prion disease comprising: a) terminating an animal; b) removing a biological sample; c) homogenizing the sample; d) treating the homogenate with immobilized proteinase-K; e) assaying the enzyme-treated homogenate using two different antibodies; f) obtaining a test result within from about 0.5 to about 20 minutes after commencing the assaying step; and g) correlating the test result.

It is unclear, based upon the description in the specification, how one obtains a test result in the time span of 0.5 to about 20 minutes after commencing the assaying step, as claimed.

Page 15, lines 15-24, of the specification appears to be contradictory in the statements put forth. The first sentence recites "The present invention allows pathogenic prion protein to be detected within from about 0.5 to about 20 minutes **after sample is introduced to the test device** and preferably within from about 5 to about 10 minutes." This appears to be when the enzyme digestion occurs within the test device.

However, the sentence on lines 20-24 recites "when the enzyme pre-treatment is conducted **separately** from the test strip, detection via the immunochromatographic phase may be yield a readable result in from about 1 to about 5 minutes **after sample introduction** and preferably from about 2 to about 10 minutes, depending upon the concentration of normal prion protein to be denatured.

It is unclear how the removal of one of the steps occurring in the test strip actually results in a longer time until a result is obtained. That is, when enzyme treatment is to occur in the test strip after sample introduction, the time is shorter than if one pretreats with enzyme prior to sample introduction.

Claim 1 does not recite a test strip or that enzyme treatment is to occur after sample introduction. Thus, it appears that claim 1 is directed to the second embodiment recited in the specification, i.e., pretreating the sample prior to assay. This method does not produce a result in the new time period range criticality in the claim, i.e., 0.5 to about 20 minutes, but a longer time period range, about 1 to about 5 minutes.

Thus, the claim is unclear concerning the type of assay and the time range resulting from this method.

Claims 2, 4-8, and 13 depend from claim 1, but do not correct the indefiniteness.

Rejection Maintained

5. The rejection of claims 1, 2, 4-8, 13-18, 20-26, and 29-34 under 35 U.S.C. 103(a) as being unpatentable over Oesch et al (*Arch, Virol.*, 16(suppl):189-195, 2000) in view of Sy et al (U.S. Pat. No. 6528269) and Grathwohl et al (*J. Virol. Meth.*, 64:205-216, 1997) is maintained.

Applicant argues that the amendments of the claims obviate the rejection.

The examiner has considered applicant's argument, but does not find it persuasive because of the indefiniteness of claim 1 as newly amended.

Claim Objections

6. Claims 3, 9-12, 19, 27, and 28 remain objected to because they depend from rejected claims.

Conclusion

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

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will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

February 3, 2006